

Dr. Cheryl van Daalen-Smith, RN, PhD, CCHN
Associate Professor, School of Nursing
School of Women's Studies
York University
4700 Keele St.
Toronto ON, M3J 1P3
Canada
cvandaal@yorku.ca

2011 JAN 25 A 8:58

Division of Dockets Management
Food and Drug Administration
5630 Fisher's Lane, rm 1061
Rockville, MD 20852

**Public Commentary to Neurological Devices Panel
of the Medical Devices Advisory Committee Meeting Announcement**
Food and Drug Administration
[Docket No. FDA-2010-N-0585]

January 12, 2011
Re: Docket No. FDA-2010-N-0585

Dear Advisory Committee,

I am an associate professor in the school of nursing at York University in Toronto, Canada. A woman who became aware of my research exploring women's experiences with ECT, asked me to submit her experience with ECT to you for your due consideration. At this time, she wishes to remain anonymous while her case is being reviewed by a local medical board, and in light of that has asked that I forward her letter/submission to you, I include it below, verbatim.

+++++

Her story follows:

"I was just an ordinary middle-aged woman, with the ordinary problems of life. At age 58 I had developed insomnia and was given a benzodiazepine for it. I had an adverse reaction which no one recognized as such. My insomnia became worse and I also became agitated. I was then diagnosed with agitated depression and prescribed a seemingly never-ending list of pharmaceuticals (35 in total in less than 8 months) which were to treat my insomnia and so-called 'depression.'

I was driven to 'dementia' by psychiatric prescribing. I started shaking and howling and my tongue darted in and out of my mouth. I could no longer stand still. I was given sleeping pills three times a day to control the agitation. I was given sleeping pills at night for sleep.

FDA-2010-N-0585

C

I was then forced to have 25 sessions of bilateral Electroconvulsive Therapy. This 'therapy' was administered three times a week. It was like being sent to death row. I was terrified. I did not know whether I was going to die from lethal injection or from electrocution.

After each 'therapy' I was totally confused. I had memory loss. I frequently had blood in my mouth. I had violent headaches. I had difficulty breathing. I developed a pronounced twitch in one foot. After each ECT session my husband had to tell me where I was, and why I was there, and to explain why I was being tortured.

My husband was advised to find a long-term institution for me. I was released from psychiatric custody. I was told that I would require drugs for the rest of my life and that I would require weekly maintenance ECT also for the rest of my life.

I tapered myself off drugs when I learned from a pharmacist that my adverse response to drugs was actually akathisia - a fairly common side-effect of a number of pharmaceuticals. The taper took several painful years.

That was six years ago. I did not go back for maintenance ECT. I take no drugs. And I am not in a long-term institution. Psychiatrists destroyed my mind, my physical health, and my emotional health with pharmaceuticals and ECT.

After ECT I could not find my way home from the hospital. I didn't know how to get into my apartment.

After ECT I lost almost total memory of over 20 years of my life. I have not regained much. After ECT I had severe headaches which lasted almost non-stop for several years. I still have pains.

After ECT my eyes were full of 'fireworks' - flashes, floaters and clouds. I have vitreal detachments.

After ECT I had heart palpitations. I still have them, though not as frequently.

After ECT I discovered damage to my teeth and to my dental restorations.

After ECT my legs tremored non-stop. They still tremor.

After ECT I had balance problems. I still have balance problems.

After ECT I had spontaneous seizures. I still have them, but less frequently. I feel weak, I lose consciousness, I collapse, I froth at the mouth, and my arms and legs spasm in all directions.

After ECT I had a pronounced twitch in one foot. It is still there, but less visible.

After ECT I had difficulty breathing. I continue to have difficulty and have just been diagnosed with an hiatus hernia which interferes with the movement of my diaphragm.

After ECT I watched my husband collapse from grief, from stress, from guilt, and from heart failure. He had been informed that ECT was safe and effective, and he had been coerced into giving approval

I breezed through high school and university. Post ECT I have difficulty learning new information. I put cork tiles on my home-office wall so I can stick up notes which remind me what I am supposed to be doing and when. I solved the New York Times Sunday crossword with ease. Post ECT I am too distressed by cognitive defects, to even attempt it. I was an avid reader. I often read a book a day. My memory was superb. Post ECT I have difficulty

concentrating and remembering what I have just read. Photography was once my livelihood. Post ECT I could no longer use my camera, because I couldn't figure out how it worked.

I no longer have insomnia. Shortly after my release from psychiatric custody I was diagnosed with hypoglycemia and a thyroid problem which were most likely the cause of the original insomnia. I do sleep, but with my fists clenched, and I whimper and sometimes wake up screaming with flashbacks of ECT. I continue to have severe PTSD. I feel as if I have been in a coma for 20 years.

Some psychiatrists try to insist that memory loss (following ECT) is actually because of depression. I wasn't even depressed until antidepressant medications were administered.

I am everywoman and I am everyman. What happened to me could happen to anyone. I will never be normal again. I am not in a long-term institution. I'm not even taking pharmaceuticals. I am alive to tell a story which must be told.

My husband is alive. Prior to my ECT experience, he had never had a sick day in his life. We didn't even have aspirin in the house. Post my ECT experience, he requires heart medication.


I was once bright, energetic, creative, trendy, slender, and light on my feet. The wife who was returned to my husband post ECT has brain damage and amnesia, is disorganized and clumsy, has tremors and seizures, has blurred vision, is overweight, and whimpers and sometimes screams in her sleep. Had he been informed of the potential for harm of this magnitude, he would never have signed the consent form.

ECT knocked out my soul, but not my spirit. Psychiatrists sentenced the wrong person to the electric chair. ANY PERSON SENTENCED TO ECT IS THE WRONG PERSON. ECT must be discontinued. It is a dangerous procedure, performed with a dangerous machine in dangerous hands. It has no place in the practice of medicine."

Please do not reduce FDA approval requirements for ECT devices.

+++++

Upon her heartfelt request that I send this to you on her behalf, for she remains fearful of speaking out about her experience, I send this to you with only good intentions. Please do not hesitate to contact me. Yours very truly,


Dr. Cheryl Van Daalen-Smith, RN, PhD

DR. C. VAN DAALEN-SMITH

4700 Keele St

301 A - LINES

TORONTO, ONTARIO



FOOD & DRUG ADMINISTRATION

DIVISION OF DOCKET MANAGEMENT

5630 FISHER'S LANE

RM 1061

ROCKVILLE, MD

20852

208529999

